

FORM PTO-1390 (Modified)
(REV 11-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

R.35252

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/890532

INTERNATIONAL APPLICATION NO.
PCT/DE 99/03324INTERNATIONAL FILING DATE
16 October 1999PRIORITY DATE CLAIMED
01 February 1999

TITLE OF INVENTION

METHOD AND APPARATUS FOR STERILIZING VESSELS OR ARTICLES

APPLICANT(S) FOR DO/EO/US

BURGER, Kurt WILKE, Bernd RAUSCHNABEL, Johannes HENKE, Sascha VOIGT, Johannes

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☒ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

Transmittal Sheets in duplicate w/fees charged to Dep.Acct. 07-2100
 Copy of German Text Application w/2 sheets drawings
 Translation of German Text Application w/2 sheets drawings
 Preliminary Amendment
 Executed Declaration (not enclosed)
 Assignment to Robert Bosch GmbH (not enclosed)
 Copy of PCT/RO/101, PCT/ISA/210, 220, PCT/IPEA/401, 409, 416

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.53) 09/890532		INTERNATIONAL APPLICATION NO. PCT/DE 99/03324		ATTORNEY'S DOCKET NUMBER R.35252	
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21. The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :			CALCULATIONS PTO USE ONLY	
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	\$1,000.00			
<input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	\$860.00			
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	\$710.00			
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	\$690.00			
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)	\$100.00			
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$860.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30		\$130.00		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	- 20 =	0	x \$18.00	\$0.00
Independent claims	- 3 =	0	x \$80.00	\$0.00
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL OF ABOVE CALCULATIONS =				\$990.00
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>				\$0.00
SUBTOTAL =				\$990.00
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30			+	\$0.00
TOTAL NATIONAL FEE =				\$990.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL FEES ENCLOSED =				\$990.00
			Amount to be:	\$
			refunded	\$
			charged	\$

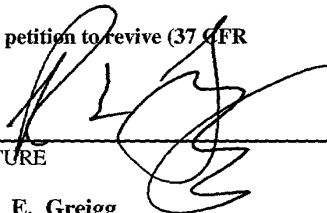
☐ A check in the amount of _____ to cover the above fees is enclosed.

☒ Please charge my Deposit Account No. **07-2100** in the amount of **\$990.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **07-2100** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

<p>Ronald E. Greigg GREIGG & GREIGG P.L.L.C. 1423 Powhatan Street Unit One Alexandria, VA 22314</p> <p>Customer No. 002119</p> <p>Telephone: (703) 838-5500 Facsimile: (703) 838-5554</p>	<p style="text-align: center;"></p> <p>SIGNATURE</p> <p>Ronald E. Greigg</p> <p>NAME</p> <p>31,517</p> <p>REGISTRATION NUMBER</p> <p>01 August 2001</p> <p>DATE</p>
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kurt BURGER et al

Based on PCT/DE 99/03324

For: Method and Apparatus for Sterilizing Vessels or Articles

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-identified application as follows:

IN THE SPECIFICATION

Delete in their entirety pages 1, 2, 4, 7, 8, 9, 14, 16, and replace these pages with new pages 1, 2, 4, 7, 8, 9, 14, 16 attached hereto as Appendix 2.

Page 17, line 1, delete "Claims" and insert --We Claim--;

IN THE CLAIMS

Please cancel claims 1-14 and add new claims 15-32.

15. A method for sterilizing vessels, including

the excitation of a plasma in or on the vessels or on the articles by electromagnetic oscillations, the method comprising the step of

- spatially and/or chronologically selectively exciting the plasma in various regions which contact walls of the vessel (2) to perform a plasma sterilization.

16. The method of claim 15, further comprising

- carrying the vessel (2) into a chamber (3), in which at least nearly a total vacuum can be produced, and that

- carrying a gas suitable for exciting a plasma into the interior of the vessel (2) via a feed line (7) shielded from the chamber (3), and establishing and maintaining a gas pressure gradient in the interior of the vessel such that a plasma is excited there and maintained for a predetermined length of time.

17. The method of claim 16, wherein

- said gas pressure gradient and said plasma in the interior of the vessel (2) are maintained by means of an adequate level of the pressure value compared to the pressure value in the chamber (3), including with a predetermined outflow of the waste gas from the vessel (2) into the chamber (3) and an ensuing evacuation by suction from the chamber (3).

18. The method of claim 16, further comprising,

- initially evacuating said chamber (3), and then introducing gas into the vessel (2) for exciting the plasma in the interior.

19. The method of claim 18, further comprising the step of

- conducting a gas for exciting a plasma into the chamber (3), for exciting a plasma in the chamber (3) and thus on the outside of the vessel (2) as well, with simultaneous extinguishing of the plasma in the interior of the vessel (2).

20. The method of claim 15, wherein

- the vessel (2) is carried into a chamber (3), into which a gas suitable for exciting a plasma is carried, and that

- in the interior of the vessel (2), via a feed line (7) shielded from the chamber (3), an at least partial evacuation can be brought about, and a gas pressure gradient is established and maintained in the interior such that there a plasma is excited and maintained for a predetermined length of time.

21. The method of claim 20, wherein

- said gas pressure gradient and said plasma in the interior of the vessel (2) are maintained by an adequate depth of the pressure value relative to the pressure value in the chamber (3), including with a predetermined inflow of the gas from the chamber (3) into the vessel (2) and an ensuing removal by suction from the vessel (2).

22. The method of claim 20, comprising,

- in a first method step, the chamber (3) is supplied with the gas, and
- in a second method step, the vessel (2) is evacuated to the extent that the excitation of the plasma in the interior is effected via the inflow of the gas out of the chamber (3).

23. The method of claim 22, wherein

- in a third method step, the gas supply into the chamber (3) is stopped, for excitation of a plasma in the chamber (3) and hence on the outside of the vessel (2) as well, with simultaneous extinguishing of the plasma in the interior of the vessel (2).

24. An apparatus for sterilizing vessels by the excitation of a plasma in or on the vessels by the spatial and/or chronological selective excitation of the plasma in various regions which contact walls of the vessel, the apparatus comprising,

- a chamber (3), a cone (4) that is open on the inside and serves as a vessel mount open which, said cone (4) having a leakage groove (5) on its outside, in the region of the seat of the vessel (2), and conduit means connected for communication via a feed line (7), with a gas supply (6) or pump (10) located outside the chamber (3);

- a pump (9) and/or a gas supply (11) connected to the chamber (3); and

- a plasma source (8) mounted on the outside of the chamber (3) and operable to excite plasma in the chamber.

25. The apparatus of claim 24, further comprising

- said leakage groove (5) is controllable with respect to the gas throughput.

26. An apparatus for sterilizing vessels by the excitation of a plasma in or on the vessels by the spatial and/or chronological selective excitation of the plasma in various regions which contact walls of the vessel, the apparatus comprising,

- chain link transportation means for supporting a plurality of vessels for transportation into the chamber (3), and a duct (23) acting as a suction removal or gas

supply rail disposed as a vessel mount, on which the vessels (2) are carried virtually in pressuretight fashion with a predetermined leakage, and said duct (23) being connected for with a gas supply (6) or pump (10) located outside the chamber (3);

- a pump (9) and/or a gas supply (11) connected to said chamber (3); and
- a plasma source (8) mounted on the outside of the chamber (3).

27. An apparatus for sterilizing vessels by the excitation of a plasma in or on the vessels by the spatial and/or chronological selective excitation of the plasma in various regions which contact walls of the vessel, the apparatus comprising,

- a transport box (30) having a plurality of holes (31) therein for receiving and transporting a plurality of vessels (2) into said chamber (3), and said vessels (2) being seated with their openings virtually in pressuretight fashion with a predetermined leakage, transport box (30) including a bottom flange for communication with a gas supply (6) or pump (10) located outside the chamber (3);

- a pump (9) and/or a gas supply (11) connected to the chamber (3); and
- a plasma source (8) mounted on the outside of the chamber (3).

28. The apparatus for performing the method, wherein

- the vessels (2) or articles to be sterilized are of glass or plastic.

29. The method of claim 17, further comprising,

- initially evacuating said chamber (3), and then introducing gas into the vessel (2) for exciting the plasma in the interior.

30. The method of claim 29, further comprising,

- initially evacuating said chamber (3), and then introducing gas into the vessel (2) for exciting the plasma in the interior.

31. The method of claim 21, comprising,

- in a first method step, the chamber (3) is supplied with the gas, and
- in a second method step, the vessel (2) is evacuated to the extent that the excitation of the plasma in the interior is effected via the inflow of the gas out of the chamber (3).

32. The method of claim 31, wherein

- in a third method step, the gas supply into the chamber (3) is stopped, for excitation of a plasma in the chamber (3) and hence on the outside of the vessel (2) as well, with simultaneous extinguishing of the plasma in the interior of the vessel (2).

IN THE ABSTRACT

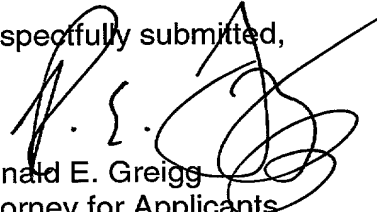
Please substitute the attached Abstract of the Disclosure for the original abstract as filed.

REMARKS

The above amendments are being made to place the application in better condition for examination.

Entry of the amendment is respectfully solicited.

Respectfully submitted,



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REG/JLB/emg

ABSTRACT OF THE DISCLOSURE

A method for sterilizing vessels or articles with which a plasma sterilization, for instance ampules in medicine, is performed, and in which a spatially and/or chronologically selective excitation of the plasma is performed in various regions that contact walls of the vessel or article. Via a feed line shielded from a chamber or via a leakage groove, a gas suitable for exciting a plasma can be delivered into the interior of the vessel, and the gas pressure gradient in the interior is established and maintained such that there or subsequently on the outer wall as well, a plasma is excited and maintained for a predetermined length of time.

Appendix 1, changes to the specification with brackets and underlining to show the changes that have been made:

Page 1, of the specification:

METHOD AND APPARATUS FOR STERILIZING VESSELS OR ARTICLES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 USC 371 application of PCT/DE 99/03324 filed on October 16, 1999.

BACKGROUND OF THE INVENTION

[Prior Art] Field of the Invention

The invention relates to a method for sterilization, preferably of vessels, and to apparatuses for performing the method [defined by the preamble to the main claim.]

Description of the Prior Art

To eliminate harmful microorganisms or germs in vessels in the medical field or in the food industry, for instance in ampules, snap-top beakers, septate beakers or so-called vials, it is well known to employ physical or chemical methods. For instance, in a steam method with precleaning using water, the vessels are exposed to hot steam over a predetermined period of time. The duration of the process requires large systems, so that high numbers of items integrated into the production flow can be sterilized. The sterilization must be effected completely, that is, all the germs must be killed. Furthermore, [the] sterilized ampules or the like have to be dried before being

[illegible]

Page 2, of the specification:

[Advantages of the Invention] SUMMARY OF THE INVENTION

A method for sterilizing vessels or articles (hereafter, vessels) is advantageously embodied according to the invention[, as defined by the characteristics of the body of the main claim,] such that a plasma sterilization is performed in which a spatially and/or chronologically selective excitation of the plasma is done in various regions that contact walls of the vessel or of the articles.

Page 4, of the specification:

In detail, in a first method step here, the chamber is supplied with the gas, and in a second method step, the vessel is evacuated to such an extent that via the [in]flow of gas out of the chamber, the excitation of the plasma in the interior is effected. In a third method step, here as well, as explained in a similar way above, the gas supply into the chamber can be stopped for excitation of the plasma on the outside of the vessel with simultaneous extinguishing of the plasma in the interior of the vessel.

Page 7, of the specification:

[These and other characteristics of preferred further features of the invention can be learned not only from the claims, including the dependent claims, but also from the description and the drawings; the individual characteristics, each alone or multiple characteristics in the form of subsidiary combinations, can be realized in the embodiment of the invention and in other fields and can represent both advantageous and independently patentable versions for which patent protection is here claimed.]

[Drawing] BRIEF DESCRIPTION OF THE DRAWINGS

[Exemplary embodiments of apparatuses for performing the method of the invention for sterilizing vessels will be described in conjunction with the drawing. Shown are:] The foregoing and other features and advantages of the invention will be apparent from the description contained below, taken in conjunction with the drawings, in which:

Fig. 1[,] is a schematic view of an apparatus according to the invention with a vessel disposed in a chamber, where a vacuum is generated in the chamber;

Fig. 2[,] is a schematic view of an apparatus according to the invention with a vessel disposed in a chamber, where a vacuum is generated in the vessel;

Fig. 3[,] is a schematic view of an exemplary embodiment of a transport apparatus for the vessels to be sterilized; and

Page 8, of the specification:

[Description of the Exemplary Embodiments] DESCRIPTION OF THE PREFERRED EMBODIMENTS

In Fig. 1, a first exemplary embodiment of an apparatus 1 for plasma sterilization of vessels 2 is shown. In a chamber 3 (in this case vacuum chamber) that can be closed off from the ambient atmosphere, the sterilization process is performed; the vessel 2 is held on a cone 4 acting as a vessel mount. The cone 4 has a leakage groove 5 on the outside, which is thus located between the inner edge of the opening of the vessel 2 seated on it and the outer wall of the cone 4 and which allows a gas flow, although slight, between the chamber 3 and the interior of the vessel 2. Because the cone 4 is open on the inside, a gas can be delivered into the vessel 2 via a feed line 7 from outside the chamber 3, under the control of a throughput regulator 6. On the outside of the chamber 3, a plasma source 8 is shown in [stylized] schematic form, for instance for generating electromagnetic alternating fields, and a pump 9 for evacuating gas from the chamber by suction is also present.

Page 9, of the specification:

In the exemplary embodiment[s] of the invention shown in Fig. 1 and in a second exemplary embodiment described hereinafter in conjunction with Fig. 2, a selective excitation of the plasma takes place. By means of different gas pressures in the interior of the vessel 2 and in the surrounding chamber 3 that are engendered at least intermittently during the method steps, the plasma can be purposefully excited either on the inside or the outside. If the pressure is too low, not enough elementary particles

can be excited or ionized to maintain a plasma discharge. If the gas pressure is too high, the mean free travel length is too short to allow the elementary particles enough acceleration distance or acceleration time between two pulses for activation or excitation and thus for ionization.

In the first exemplary embodiment of Fig. 1, the chamber 3 is pumped out using the pump 9 in such a way that the gas pressure in [its] the interior of the chamber 3 is too low to excite a plasma. In the chamber 3, the vessels 2 to be sterilized are held in such a way that they are seated by positive engagement directly with their opening on the cone 4. Via the feed line 7, a defined gas flow, for instance comprising oxygen, filtered air, steam, hydrogen peroxide vapor, argon, nitrogen, tetrafluoromethane, sulfur hexafluoride or the like, flows from outside the chamber, controlled by the throughput regulator 6, through the interior of the cone 4 into the vessel 2. This gas flow is set such that in the interior of the vessel 2, the pressure becomes so high that a plasma can be excited.

Page 14, of the specification:

In the exemplary embodiment of Fig. 3, the vessels 2 to be sterilized can be inserted out of the line one by one into links 20 of a chain 21, which as they revolve around a deflection roller 22 perform the transportation into the chamber 3 (see Figs. 1 and 2) and out of it again. Furthermore, the chain links 20 are shaped in such a way that they perform the task of sealing off the vessels 2 from the pressure stage of rough/fine (low/high) vacuum.

Page 16, after the last paragraph insert the following paragraph:

The foregoing relates to preferred exemplary of embodiments of the invention, it being understood that other variants and embodiments thereof are possible within the spirit and scope of the invention, the latter being defined by the appended claims.

039740-2E306360

Appendix 2, new pages 1, 2, 4, 7, 8, 9, 14, 16 of the specification:

METHOD AND APPARATUS FOR STERILIZING VESSELS OR ARTICLES
CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 USC 371 application of PCT/DE 99/03324 filed on October
5 16, 1999.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a method for sterilization, preferably of vessels, and to
apparatuses for performing the method.

10 Description of the Prior Art

To eliminate harmful microorganisms or germs in vessels in the medical field or in
the food industry, for instance in ampules, snap-top beakers, septate beakers or so-called
vials, it is well known to employ physical or chemical methods. For instance, in a steam
method with precleaning using water, the vessels are exposed to hot steam over a
15 predetermined period of time. The duration of the process requires large systems, so that
high numbers of items integrated into the production flow can be sterilized. The
sterilization must be effected completely, that is, all the germs must be killed.
Furthermore, sterilized ampules or the like have to be dried before being filled, which
additionally increases the system volume because of the dryer unit thus required. This
20 steam sterilization is not capable, however, of completely removing pyrogenic
decomposition products, that is, such problems that cause infection, and cell residues of
killed germs.

From European Patent Disclosure EP 0 377 788 A1, a method is known in which
for sterilizing articles, a plasma is generated with an electromagnetic radiation at a
25 frequency of

about 2.45 GHz. To that end, the article is exposed entirely to a low-pressure plasma, and in an expansion is also irradiated with an additional heat source.

SUMMARY OF THE INVENTION

A method for sterilizing vessels or articles (hereafter, vessels) is advantageously embodied according to the invention such that a plasma sterilization is performed in which a spatially and/or chronologically selective excitation of the plasma is done in various regions that contact walls of the vessel or of the articles.

With the invention, it is possible in a simple way to integrate germ killing and the complete removal of pyrogenic elements into a single method, with the method safety being assured to a high degree. The plasma sterilization according to the invention makes it possible, with very short process times, for the killing of germs and the complete elimination of the pyrogenic elements mentioned above to be done simultaneously with the performance of the method in the interior as well as on the outer wall of the vessels. A concluding drying of the vessels is unnecessary.

In a first embodiment, the vessel is carried into a chamber in which at least virtually a vacuum can be produced. Into the interior of the vessel, in a simple way, via a feed

In a second advantageous embodiment of the method of the invention, the vessel is carried into a chamber into which the gas suitable for exciting the plasma is carried. In the interior of the vessel, via a feed line shielded from the chamber, an at least partial evacuation can now be produced; the gas pressure gradient in the interior is established and maintained such that a plasma is excited here and maintained for a predetermined length of time.

In this process, which is the inverse of the first embodiment of the method, the gas pressure gradient and the plasma in the interior of the vessel are thus maintained by an adequate depth of the pressure value compared to the pressure value in the chamber, with a predetermined inflow of the gas out of the chamber into the vessel and an ensuing removal from the vessel by suction.

In detail, in a first method step here, the chamber is supplied with the gas, and in a second method step, the vessel is evacuated to such an extent that via the flow of gas out of the chamber, the excitation of the plasma in the interior is effected. In a third method step, here as well, as explained in a similar way above, the gas supply into the chamber can be stopped for excitation of the plasma on the outside of the vessel with simultaneous extinguishing of the plasma in the interior of the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the invention will be apparent from the description contained below, taken in conjunction with the drawings, in which:

5 Fig. 1 is a schematic view of an apparatus according to the invention, with a vessel disposed in a chamber, where a vacuum is generated in the chamber;

Fig. 2 is a schematic view of an apparatus according to the invention, with a vessel disposed in a chamber, where a vacuum is generated in the vessel;

10 Fig. 3 is a schematic view of an exemplary embodiment of a transport apparatus for the vessels to be sterilized; and

Fig. 4, a schematic view of a transport apparatus with a transport box for the vessels to be sterilized.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In Fig. 1, a first exemplary embodiment of an apparatus 1 for plasma sterilization of vessels 2 is shown. In a chamber 3 (in this case vacuum chamber) that can be closed off from the ambient atmosphere, the sterilization process is performed; the vessel 2 is held on a cone 4 acting as a vessel mount. The cone 4 has a leakage groove 5 on the outside, which is thus located between the inner edge of the opening of the vessel 2 seated on it and the outer wall of the cone 4 and which allows a gas flow, although slight, between the chamber 3 and the interior of the vessel 2. Because the cone 4 is open on the inside, a gas can be delivered into the vessel 2 via a feed line 7 from outside the chamber 3, under the control of a throughput regulator 6. On the outside of the chamber 3, a plasma source 8 is shown in schematic form, for instance for generating electromagnetic alternating fields, and a pump 9 for evacuating gas from the chamber by suction is also present.

The principle of the sterilization method employed here is based on a physical process known per se, which leads to the generation of a plasma from a permanent gas, in which by a suitable delivery of energy the atoms of the gas are converted into a mixture of electrons and ions. The delivery

of energy takes place here preferably by means of the acceleration of the charge carriers of the elementary particles, in particular the electrons, in electrical fields that are impressed on the plasma from outside by the plasma source 8.

In the exemplary embodiment of the invention shown in Fig. 1 and in a second
5 exemplary embodiment described hereinafter in conjunction with Fig. 2, a selective excitation of the plasma takes place. By means of different gas pressures in the interior of the vessel 2 and in the surrounding chamber 3 that are engendered at least intermittently during the method steps, the plasma can be purposefully excited either on the inside or the outside. If the pressure is too low, not enough elementary particles
10 can be excited or ionized to maintain a plasma discharge. If the gas pressure is too high, the mean free travel length is too short to allow the elementary particles enough acceleration distance or acceleration time between two pulses for activation or excitation and thus for ionization.

In the first exemplary embodiment of Fig. 1, the chamber 3 is pumped out using
15 the pump 9 in such a way that the gas pressure in the interior of the chamber 3 is too low to excite a plasma. In the chamber 3, the vessels 2 to be sterilized are held in such a way that they are seated by positive engagement directly with their opening on the cone 4. Via the feed line 7, a defined gas flow, for instance comprising

vessels 2 are fed in through a permanently present opening, and the opening should, for the sake of achieving minimal leakage, as much as possible be equivalent to the outline of the vessels 2 to be infed. The pump configuration must be designed as extremely strong, so that the requisite vacuum can be achieved in the interior of the vacuum system in what in this case are relatively large volumes of the chamber 3, and in a combination with the variant method of Fig. 2, a substantially lesser pump capacity suffices, since only the small volume of the vessels has to be evacuated by suction.

In the exemplary embodiment of Fig. 3, the vessels 2 to be sterilized can be inserted out of the line one by one into links 20 of a chain 21, which as they revolve around a deflection roller 22 perform the transportation into the chamber 3 (see Figs. 1 and 2) and out of it again. Furthermore, the chain links 20 are shaped in such a way that they perform the task of sealing off the vessels 2 from the pressure stage of rough/fine (low/high) vacuum.

For the sake of clarification, the right-hand portion of Fig. 3 shows a section through a vessel 2, which is located in the chain 21 or in a chain link 20. The chain 21 is guided in an oblong slot, the width of which is adapted to the diameter of the vessels 2 to be sterilized, of a square profile 23, which serves as a common suction evacuation line for the individual vessels 2 and also takes on the task of sealing off from the pressure stage. Since here both sealing elements,

by suction is performed until such time as a pressure range is attained in which the ignition of the plasma can take place. The outfeeding of the vessels 2 takes place here in a corresponding way to the infeeding.

The foregoing relates to preferred exemplary of embodiments of the invention,
5 it being understood that other variants and embodiments thereof are possible within the spirit and scope of the invention, the latter being defined by the appended claims.

2/PRTS

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METHOD AND APPARATUS FOR STERILIZING VESSELS OR ARTICLES

Prior Art

The invention relates to a method for sterilization, preferably of vessels, and to apparatuses for performing the method defined by the preamble to the main claim.

To eliminate harmful microorganisms or germs in vessels in the medical field or in the food industry, for instance in ampules, snap-top beakers, septate beakers or so-called vials, it is well known to employ physical or chemical methods. For instance, in a steam method with precleaning using water, the vessels are exposed to hot steam over a predetermined period of time. The duration of the process requires large systems, so that high numbers of items integrated into the production flow can be sterilized. The sterilization must be effected completely, that is, all the germs must be killed.

Furthermore, the sterilized ampules have to be dried before being filled, which additionally increases the system volume because of the dryer unit thus required. This steam sterilization is not capable, however, of completely removing pyrogenic decomposition products, that is, such problems that cause infection, and cell residues of killed germs.

From European Patent Disclosure EP 0 377 788 A1, a method is known in which for sterilizing articles, a plasma is generated with an electromagnetic radiation at a frequency of

about 2.45 GHz. To that end, the article is exposed entirely to a low-pressure plasma, and in an expansion is also irradiated with an additional heat source.

Advantages of the Invention

5 A method for sterilizing vessels or articles is advantageously embodied according to the invention, as defined by the characteristics of the body of the main claim, such that a plasma sterilization is performed in which a spatially and/or chronologically selective excitation of the plasma is
10 done in various regions that contact walls of the vessel or of the articles.

With the invention, it is possible in a simple way to integrate germ killing and the complete removal of pyrogenic elements into a single method, with the method safety being
15 assured to a high degree. The plasma sterilization according to the invention makes it possible, with very short process times, for the killing of germs and the complete elimination of the pyrogenic elements mentioned above to be done simultaneously with the performance of the method in the
20 interior as well as on the outer wall of the vessels. A concluding drying of the vessels is unnecessary.

In a first embodiment, the vessel is carried into a chamber in which at least virtually a vacuum can be produced. Into the interior of the vessel, in a simple way, via a feed

line shielded from the chamber, a gas suitable for exciting the plasma can be carried, and the gas pressure gradient in the interior is established and maintained such that only here is a plasma excited and maintained for a predetermined length of time. The gas pressure gradient and the plasma in the interior of the vessel, in this advantageous embodiment, are maintained by an adequate magnitude of the pressure value compared to the pressure value in the chamber, including with a predetermined outflow of the waste gas from the vessel into the chamber, and an ensuing removal from the chamber by suction.

Via the partial pressure values of the gas, the excitation of the plasma can advantageously be controlled. If the pressure is too low, not enough elementary particles can be excited or ionized to maintain a plasma discharge. If the pressure of the gas is too high, the mean free travel length is too short to effect an activation or excitation of the elementary particles.

In detail, in a first method step, the chamber can be evacuated, and in a second method step, the gas can be introduced into the vessel to excite the plasma in the interior. In a third method step, it is furthermore possible thereafter to carry the gas into the chamber to excite the plasma in the chamber and to carry it on the outside of the vessel with simultaneous extinguishing of the plasma in the interior of the vessel.

In a second advantageous embodiment of the method of the invention, the vessel is carried into a chamber into which the gas suitable for exciting the plasma is carried. In the interior of the vessel, via a feed line shielded from the chamber, an at least partial evacuation can now be produced; the gas pressure gradient in the interior is established and maintained such that a plasma is excited here and maintained for a predetermined length of time.

In this process, which is the inverse of the first embodiment of the method, the gas pressure gradient and the plasma in the interior of the vessel are thus maintained by an adequate depth of the pressure value compared to the pressure value in the chamber, with a predetermined inflow of the gas out of the chamber into the vessel and an ensuing removal from the vessel by suction.

In detail, in a first method step here, the chamber is supplied with the gas, and in a second method step, the vessel is evacuated to such an extent that via the inflow of gas out of the chamber, the excitation of the plasma in the interior is effected. In a third method step, here as well, as explained in a similar way above, the gas supply into the chamber can be stopped for excitation of the plasma on the outside of the vessel with simultaneous extinguishing of the plasma in the interior of the vessel.

This last, so-called inverse principle has the advantage that only the lesser volume, namely only the interior of the vessel to be sterilized, has to be evacuated by suction, while initially a rough vacuum in the chamber is adequate. Only in
5 the second method step is the chamber evacuated by suction.

In an especially advantageous apparatus for performing the method of the invention, the vessel is seated in the chamber on a cone, acting as a vessel mount, that is open on the inside. On the outside, in the region of the seat of what
10 in this case is an open vessel, the cone has a leakage groove, and on the inside it can be made to communicate, via a feed line, with a gas supply or pump located outside the chamber. A pump for evacuation and/or a gas supply for the gas to be excited can be connected to the chamber. A plasma source,
15 preferably for emitting microwave energy, is mounted on the outside of the chamber. The frequency of the microwave radiation can preferably be in a range of 4.9 GHz.

To make it possible to sterilize many vessels, the vessels can advantageously be inserted into links of a chain
20 for transportation into the chamber. As the vessel mount, a square acting as a suction evacuation or gas supply rail is present here, on which the vessels are carried virtually in pressureproof fashion, with a predetermined leakage. The square communicates with a gas supply or pump located outside
25 the chamber, as described above.

In a further, automatable apparatus, many vessels are advantageously introduced into holes in a transport box for transportation into the chamber, optionally by means of an automatic manipulator or robot. The vessels are seated in the holes with their openings in virtually pressureproof fashion, with a predetermined leakage. The transport box can be connected via a bottom flange to a gas supply or pump located outside the chamber, as above.

With the invention, with the inclusion of the apparatuses for performing the sterilization method, the system volume can advantageously be kept low, for a high number of items to be sterilized per unit of time. The capital expense for the apparatuses is low in comparison with conventional versions, and in particular a continuous production flow in the performance of the method is feasible.

With the invention, virtually certain control of the sterilization can be achieved in a simple way. The illumination of the plasma merely has to be monitored by simple optical means, in order to gain a definitive finding as to the sterilization. By using a low-temperature plasma with a gas suitable for this purpose, it is also possible to sterilize plastic vessels or articles using the method of the invention, since the incident temperatures are then as a rule less than 150°C.

These and other characteristics of preferred further features of the invention can be learned not only from the claims, including the dependent claims, but also from the description and the drawings; the individual characteristics, each alone or multiple characteristics in the form of subsidiary combinations, can be realized in the embodiment of the invention and in other fields and can represent both advantageous and independently patentable versions for which patent protection is here claimed.

Drawing

Exemplary embodiments of apparatuses for performing the method of the invention for sterilizing vessels will be described in conjunction with the drawing. Shown are:

Fig. 1, a schematic view of an apparatus with a vessel disposed in a chamber, where a vacuum is generated in the chamber;

Fig. 2, a schematic view of an apparatus with a vessel disposed in a chamber, where a vacuum is generated in the vessel;

Fig. 3, a schematic view of an exemplary embodiment of a transport apparatus for the vessels to be sterilized; and

Fig. 4, a schematic view of a transport apparatus with a transport box for the vessels to be sterilized.

Description of the Exemplary Embodiments

In Fig. 1, a first exemplary embodiment of an apparatus 1 for plasma sterilization of vessels 2 is shown. In a chamber 3 (in this case vacuum chamber) that can be closed off from the ambient atmosphere, the sterilization process is performed; the vessel 2 is held on a cone 4 acting as a vessel mount. The cone 4 has a leakage groove 5 on the outside, which is thus located between the inner edge of the opening of the vessel 2 seated on it and the outer wall of the cone 4 and which allows a gas flow, although slight, between the chamber 3 and the interior of the vessel 2. Because the cone 4 is open on the inside, a gas can be delivered into the vessel 2 via a feed line 7 from outside the chamber 3, under the control of a throughput regulator 6. On the outside of the chamber 3, a plasma source 8 is shown in stylized form, for instance for generating electromagnetic alternating fields, and a pump 9 for evacuating gas from the chamber by suction is also present.

The principle of the sterilization method employed here is based on a physical process known per se, which leads to the generation of a plasma from a permanent gas, in which by a suitable delivery of energy the atoms of the gas are converted into a mixture of electrons and ions. The delivery

of energy takes place here preferably by means of the acceleration of the charge carriers of the elementary particles, in particular the electrons, in electrical fields that are impressed on the plasma from outside by the plasma source 8.

In the exemplary embodiments of the invention shown in Fig. 1 and in a second exemplary embodiment described hereinafter in conjunction with Fig. 2, a selective excitation of the plasma takes place. By means of different gas pressures in the interior of the vessel 2 and in the surrounding chamber 3 that are engendered at least intermittently during the method steps, the plasma can be purposefully excited either on the inside or the outside. If the pressure is too low, not enough elementary particles can be excited or ionized to maintain a plasma discharge. If the gas pressure is too high, the mean free travel length is too short to allow the elementary particles enough acceleration distance or acceleration time between two pulses for activation or excitation and thus for ionization.

In the first exemplary embodiment of Fig. 1, the chamber 3 is pumped out using the pump 9 in such a way that the gas pressure in its interior of the chamber 3 is too low to excite a plasma. In the chamber 3, the vessels 2 to be sterilized are held in such a way that they are seated by positive engagement directly with their opening on the cone 4. Via the feed line 7, a defined gas flow, for instance comprising

oxygen, filtered air, steam, hydrogen peroxide vapor, argon, nitrogen, tetrafluoromethane, sulfur hexafluoride or the like, flows from outside the chamber, controlled by the throughput regulator 6, through the interior of the cone 4 into the vessel 2. This gas flow is set such that in the interior of the vessel 2, the pressure becomes so high that a plasma can be excited.

To obtain a desired pressure gradient, or at a defined pressure obtain a defined gas exchange in the vessel 2 of Fig. 1, the gas, or the waste gas from the plasma, is evacuated by suction from the vessel 2 into the chamber 3 via the leakage groove 5 on the outside of the cone 4. As a function of the quantity of gas flowing in through the cone 4 and of the guide value of the leakage groove 5, the pressure of the gas in the vessel 2 can be established. A controlled leakage groove, for instance with a valve, is also possible here. The waste gas that has flowed into the chamber 3 through the leakage groove 5 is then evacuated by suction from the chamber 3 by the pump 9 in order to maintain the pressure ratios, and as a result, a plasma is thus generated selectively only in the interior of the vessel 2 to be sterilized.

In an especially advantageous refined version of this selective sterilization process, the chamber 3 of Fig. 1 is first pumped out completely, without allowing a gas flow into the vessel 2 or into the chamber 3. Next, the throughput regulator 6 is opened to generate a defined gas flow, which

flows into the vessel 2 to be sterilized and in the interior of the vessel 2 ignites a plasma, advantageously by means of microwave emission from the plasma source 8.

Once the desired sterilization effect in the interior of the vessel 2 is reached, it is optionally also possible in the chamber 3, that is, outside the vessel 2 to be sterilized, to raise the gas pressure by having a defined flow of the same gas or gas mixture that flows through the feed line 7, or optionally through an additional feed as well, not shown here, to be let into the chamber 3, so that a plasma can be excited here as well. The plasma is extinguished in the interior of the vessel 2 then and is excited outside, in the chamber 3. With this method step, the vessel 2 can thus also be sterilized on the outer wall, oriented toward the chamber 3.

This process, described above, of the outward propagation of the plasma formation occurs because a plasma shields itself off from the outside, that is, absorbs the energy emitted into it, to such an extent that the energy outside this plasma is not sufficient to excite a further plasma. Thus the outer plasma in the chamber 3 is shielded from the partitioned-off gas atmosphere in the interior of the vessel 2 to be sterilized and prevents the excitation of a plasma there. If the pressure in the chamber 3 is too low, but if the pressure in the interior of the vessel is adequate for a plasma, then the energy emitted into it is largely absorbed in the inner plasma of the vessel 2. However, in the other case, since the

energy of the plasma source 8 is first emitted into the chamber 3, and only then (possibly damped by the wall of the vessel 2 to be sterilized) does it reach the interior of the vessel 2, the plasma is created immediately on the outside of the vessel 2, as soon as the gas pressure for this purpose is adequate in the chamber 3.

In the second exemplary embodiment of Fig. 2, the principle described in conjunction with Fig. 1 is reversed; the components functioning substantially the same, however, are provided with the same reference numerals as in Fig. 1. The vessel 2 to be sterilized is evacuated by suction here directly via the cone 4 using a pump 10, to form a vacuum in the vessel 2. The performance of the sterilization method with this exemplary embodiment now takes place in such a way that once the chamber 3 has been flooded with the sterilization gas or gas mixture through a gas supply 11, the vessel 2 to be sterilized is pumped out to such an extent that a plasma for emission of an electromagnetic field, advantageously a microwave field, in the interior of the vessel 2 is excited, while the pressure outside the vessel 2 to be sterilized, in the chamber 3, is too high for a plasma (see the explanation earlier above). The gas then flows through the leakage groove 5 on the cone 4 of the vessel mount into the vessel 2. The waste gas in the vessel 2 can now be evacuated by suction through the cone 4 and the feed line 7 by the pump 10.

In a subsequent method step, for sterilizing the outer surfaces of the vessel 2, the chamber 3 is evacuated by suction to such an extent that the plasma combusts on the outside in the chamber 3. This can be effected by providing that the delivery of fresh gas is stopped by the throughput regulator of the gas supply 11, and the gas from the chamber 3 is gradually evacuated by suction via the leakage groove 5 on the cone 4, until the appropriate pressure is reached in the chamber 3. This can also be accomplished alternatively with pumps, not shown here, with which the chamber 3 can be evacuated as well.

Sterilization of individual vessels in a relatively simple apparatus has been described in terms of the exemplary embodiments above. However, the method of the invention can also be integrated into an at least partly automated process, in which many vessels 2 are fed into and out of the chamber 3, either continuously in series or sequentially in batches but at a cadence predetermined by the particular production line.

In the case of exemplary embodiments for performing such a method, some infeeding techniques for the vessels 2 will now be described in conjunction with Figs. 3 and 4; these techniques make the great pressure jump between the ambient atmosphere and the vacuum in the chamber 3 possible for a relatively large volume. This can in general be either a mechanical sluice device, such as doors or slides, or a differentially pumped system configuration, in which the

vessels 2 are fed in through a permanently present opening, and the opening should, for the sake of achieving minimal leakage, as much as possible be equivalent to the outline of the vessels 2 to be infed. The pump configuration must be designed as extremely strong, so that the requisite vacuum can be achieved in the interior of the vacuum system in what in this case are relatively large volumes of the chamber 3, and in a combination with the variant method of Fig. 2, a substantially lesser pump capacity suffices, since only the small volume of the vessels has to be evacuated by suction.

In the exemplary embodiment of Fig. 3, the vessels 2 to be sterilized can be inserted out of the line one by one into links 20 of a chain 21, which as they revolve around a deflection roller 22 perform the transportation into the chamber 3 (see Figs. 1 and 2) and out of it again. Furthermore, the chain links 20 are shaped in such a way that they perform the task of sealing off the vessels 2 from the pressure stage of rough/fine vacuum.

For the sake of clarification, the right-hand portion of Fig. 3 shows a section through a vessel 2, which is located in the chain 21 or in a chain link 20. The chain 21 is guided in an oblong slot, the width of which is adapted to the diameter of the vessels 2 to be sterilized, of a square profile 23, which serves as a common suction evacuation line for the individual vessels 2 and also takes on the task of sealing off from the pressure stage. Since here both sealing elements,

namely the chain 21 and the square profile 23, have leakages, an adequate pumping capacity of a pump 24 must be made available. The apparatus itself can be operated at a rough vacuum or even at atmospheric pressure.

5 In the second exemplary embodiment for sterilization of many vessels 2 in Fig. 4, the plasma sterilization of the vessels 2 takes place in groups, which are fitted into a transport box 30. For example, the individual vessels 2 can be inserted into the transport box 30 by an automatic
10 manipulator, and the transport box can for instance be a rectangular special steel container, into whose cover plate holes 31 are stamped. The diameter of these holes 31 is selected such that the conical vessels 2 (such as glass or plastic ampules), which are inserted into the holes 31,
15 virtually seal off these holes.

The bottom plate of the special steel container of the transport box 30 here has a flange 32, by way of which the coupling to the gas supply, in the version of Fig. 1, or to the pump flange, in the version of Fig. 2, takes place. The
20 transport box 30 equipped in this way is then fed, via a door or a plate valve, not shown here, into an antechamber of the vacuum system, which also contains the chamber 3; the doors are closed, and the antechamber is pumped out. What is done next in the vacuum system is the transfer from the antechamber
25 into the chamber 3 or into a corresponding chamber region, where the evacuation by suction is performed. The evacuation

by suction is performed until such time as a pressure range is attained in which the ignition of the plasma can take place. The outfeeding of the vessels 2 takes place here in a corresponding way to the infeeding.

[illegible]

the excitation of a plasma in the vessels or on the articles by electromagnetic oscillations, characterized in that

2. The method of claim 1, characterized in that

- a gas suitable for exciting a plasma is carried into the interior of the vessel (2) via a feed line (7) shielded from the chamber (3), and a gas pressure gradient is established and maintained in the interior such that a plasma is excited there and maintained for a predetermined length of time.

- the gas pressure gradient and the plasma in the

- in the interior of the vessel (2), via a feed line (7) shielded from the chamber (3), an at least partial evacuation can be brought about, and a gas pressure gradient is established and maintained in the interior such that there a plasma is excited and maintained for a predetermined length of time.

7. The method of claim 6, characterized in that

- the gas pressure gradient and the plasma in the interior of the vessel (2) are maintained by an adequate depth of the pressure value relative to the pressure value in the chamber (3), including with a predetermined inflow of the gas from the chamber (3) into the vessel (2) and an ensuing removal by suction from the vessel (2).

8. The method of claim 6 or 7, characterized in that

- in a first method step, the chamber (3) is supplied with the gas, and that

- in a second method step, the vessel (2) is evacuated to the extent that the excitation of the plasma in the interior is effected via the inflow of the gas out of the chamber (3).

9. The method of claim 8, characterized in that

- in a third method step, the gas supply into the chamber

(3) is stopped, for excitation of a plasma in the chamber (3) and hence on the outside of the vessel (2) as well, with simultaneous extinguishing of the plasma in the interior of the vessel (2).

10. An apparatus for performing the method of one of the foregoing claims, characterized in that

- the vessel (2) in the chamber (3) is seated on a cone (4) that is open on the inside and serves as a vessel mount, and the cone (4) has a leakage groove (5) on the outside, in the region of the seat of the vessel (2), and on the inside can be made to communicate, via a feed line (7), with a gas supply (6) or pump (10) located outside the chamber (3); that

- a pump (9) and/or a gas supply (11) can be connected to the chamber (3); and that

- a plasma source (8) is mounted on the outside of the chamber (3).

11. The apparatus of claim 10, characterized in that

- the leakage groove (5) is controllable with respect to the gas throughput.

12. The apparatus for performing the method of one of claims 1-9, characterized in that

- many vessels (2) can be introduced into links (20) of a chain (21) for transportation into the chamber (3), and a square (23) acting as a suction removal or gas supply rail is disposed as a vessel mount, on which the vessels (2) are carried virtually in pressuretight fashion with a predetermined leakage, and the square (23) can be made to communicate with a gas supply (6) or pump (10) located outside the chamber (3); that

- a pump (9) and/or a gas supply (11) can be connected to the chamber (3); and that

- a plasma source (8) is mounted on the outside of the chamber (3).

13. The apparatus for performing the method of one of claims 1-9, characterized in that

- many vessels (2) can be introduced into holes (31) of a transport box (30) for transportation into the chamber (3), and the vessels (2) are seated with their openings virtually in pressuretight fashion with a predetermined leakage, and the transport box (30) can be made to communicate via a bottom flange (32) with a gas supply (6) or pump (10) located outside the chamber (3); that

- a pump (9) and/or a gas supply (11) can be connected to the chamber (3); and that

- a plasma source (8) is mounted on the outside of the chamber (3).

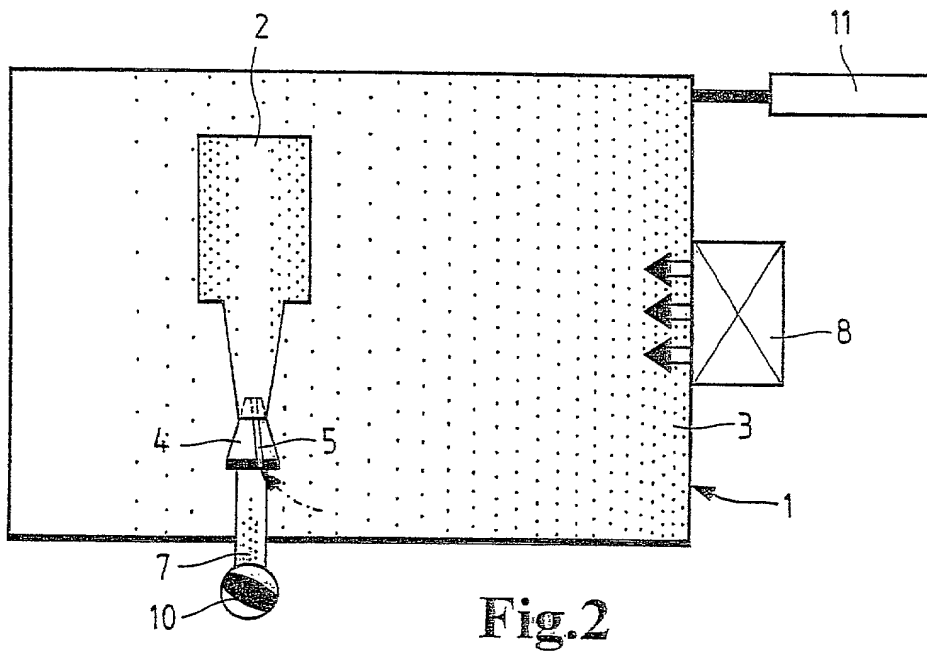
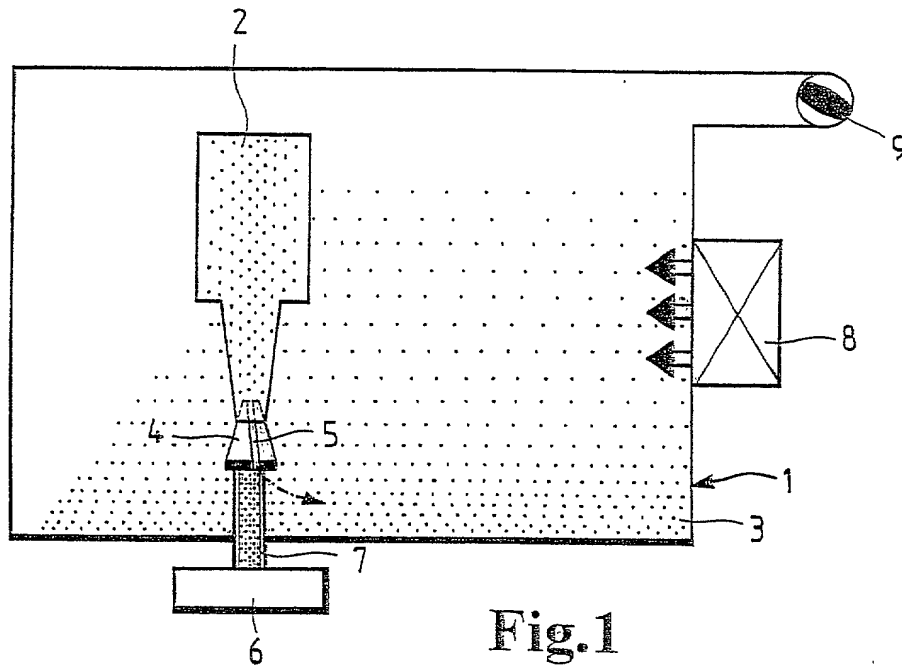
14. The apparatus for performing the method of one of claims 1-9, or one of claims 10-13, characterized in that

- the vessels (2) or articles to be sterilized are of glass or plastic.

Abstract

A method for sterilizing vessels or articles is proposed, with which a plasma sterilization, for instance of ampules in medicine, is performed, and in which a spatially and/or
5 chronologically selective excitation of the plasma is performed in various regions that contact walls of the vessel (2) or article. Via a feed line (7) shielded from a chamber (3) or via a leakage groove (5), a gas suitable for exciting a plasma can be delivered into the interior of the vessel (2),
10 and the gas pressure gradient in the interior is established and maintained such that there or subsequently on the outer wall as well, a plasma is excited and maintained for a predetermined length of time.

(Fig. 1)



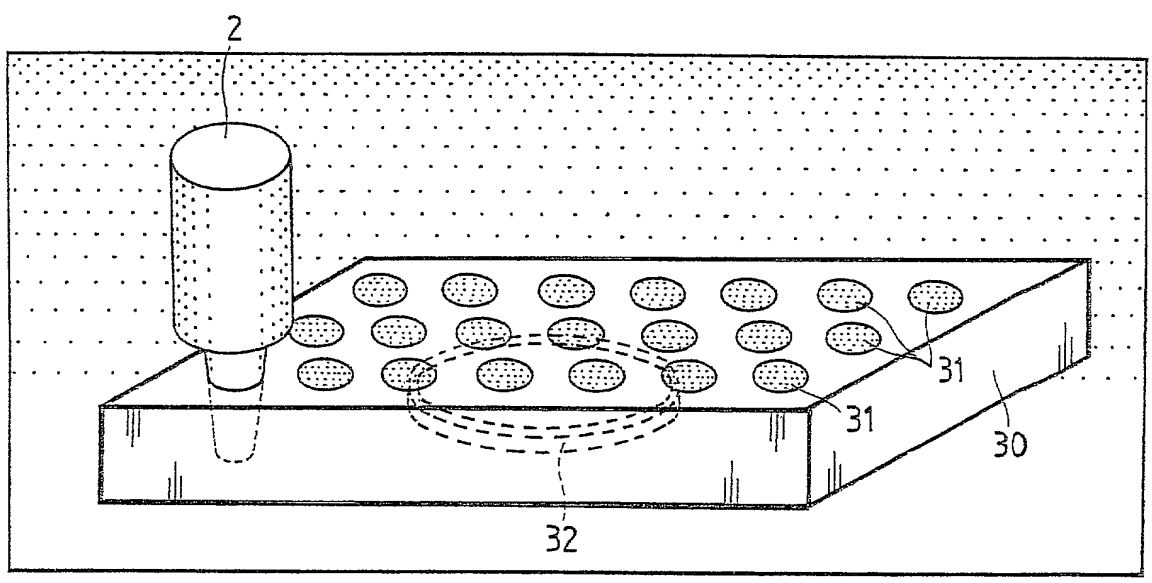
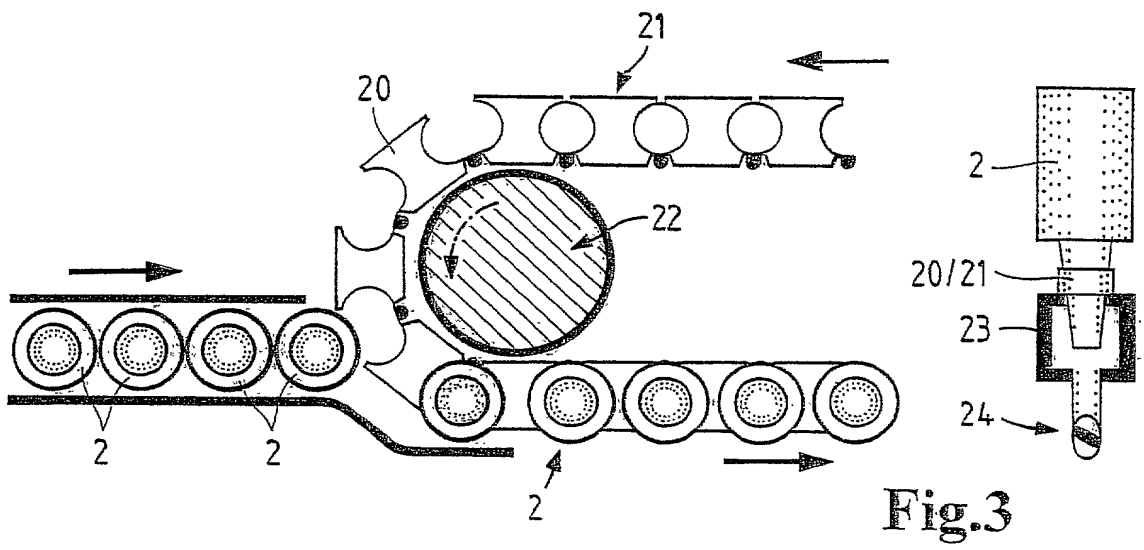
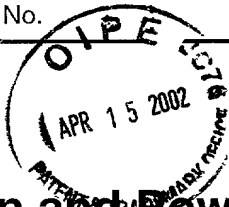


Fig. 4

205410-26906860


Docket No.
R.35252

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHOD AND APPARATUS FOR STERILIZING VESSELS OR ARTICLES

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on 16 OCTOBER 1999 as United States Application No. or PCT International Application Number PCT/DE 99/03324 and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)	Priority	Claimed
<u>1 99 03 935.6</u> (Number)	<u>GERMANY</u> (Country)	<u>01 FEBRUARY 1999</u> (Day/Month/Year Filed)
		<input checked="" type="checkbox"/>
<u> </u> (Number)	<u> </u> (Country)	<u> </u> (Day/Month/Year Filed)
		<input type="checkbox"/>
<u> </u> (Number)	<u> </u> (Country)	<u> </u> (Day/Month/Year Filed)
		<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

_____	_____
(Application Serial No.)	(Filing Date)
_____	_____
(Application Serial No.)	(Filing Date)
_____	_____
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)
_____	_____	_____
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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